U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

March 10, 1998

The Honorable Carol M. Browner
Administrator
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Administrator Browner:

In the 19 months since enactment of the Food Quality Protection Act (FQPA), we have observed with great interest the activities undertaken by the Environmental Protection Agency (EPA) to implement this legislation. We were pleased that EPA moved quickly to issue a set of Guiding Principles to guide the agency's implementation, and we support those principles. The purpose of this letter is to indicate our continuing interest in your progress, to inquire about any obstacles you may be facing in achieving the goals of the legislation, and to ask that you comment on the extent to which the agency's activities are consistent with your principles.

Specifically, we request that you address the following:

1. **Sound Science**: Congressional intent was that implementation of this new law be based on the best available science, and specifically, as the legislative language states, on "reliable and available" information, including "such information as the administrator may require." We provided a new authority for the Administrator to require registrants to submit additional data concerning tolerances in a timely manner. We intended that the data call-in authority be used, for example, to allow EPA, in conducting exposure assessments, to use actual or anticipated pesticide residue levels in food, rather than default assumptions, and subsequently to obtain complete residue information to demonstrate that actual levels are not above those anticipated. This authority positions the agency well to require and obtain real data, rather than to rely on assumptions and defaults. The use of unrealistic, inappropriate assumptions, such as computer models that estimate drinking water exposures based on farm ponds, was never intended. The use of such unsound information will not further the public health, and could seriously jeopardize American food production. This is why the FQPA emphasized the Administrator's authority to

secure data, registrants' responsibility to provide the data, and the need to use those data in decision-making.

2. **Health-Based Approaches to Food Safety**: The Congress overwhelmingly supported the provisions of FQPA that strengthened science and health-based approaches to setting safe levels of pesticide residues in food. We recognized that science had long since outpaced the Delaney Clause, and that flexibility was essential to allow the agency to adapt to advancements in scientific knowledge.

Recommendations of the 1993 NAS report, Pesticides in the Diets of Infants and Children, were carefully considered in the drafting of FQPA. Among other recommendations, the study states:

> "... the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal development toxicity should also be considered when there is evidence of postnatal development toxicity and when data from toxicity testing relative to children are incomplete. The committee wishes to emphasize that this is not a new, additional uncertainty factor but, rather, an extended application of an uncertainty factor now routinely used by the agencies for a narrower purpose."

Several key parts of that statement bear emphasis. First, the NAS committee recommended that the "traditionally used" up to 10-fold factor continue to be used when data are incomplete. Second, the committee emphasized that such an uncertainty factor "is not a new, additional" factor.

In her July 23, 1996, letters to Senator Lugar and Chairman Bliley, Deputy Administrator Goldman clarified these points, indicating that EPA's interpretation of the statutory language was that the agency should continue its current approach. This was consistent with our intent, and we continue to expect EPA's implementation of FQPA to follow this approach.

Relative to cancer risk, the FQPA purposefully excludes a "bright-line" definition of an acceptable lifetime risk, allowing for future advancements in quantitative risk assessment methods. We want to emphasize our continuing belief that attempting to develop a bright line at this point would be inconsistent with good science, as well as with long-standing policy. Furthermore, if or when, in the future, the science of risk assessment were to allow for the potential of such a "bright line," we would expect the agency to engage in appropriate rulemaking.

One of the hallmarks of the FQPA was its adoption of sound health-based approaches to food safety. This includes estimating exposures of the entire populations, including sensitive sub-populations, to pesticide residues from a variety of sources. Such estimates, of course, logically focus on upper limit exposures from food and water consumption data and other sources.

However, in keeping with FQPA's central theme of science-based decision-making, it is critically important to confirm the statistical reliability of upper-limit exposure information before making a regulatory decision. Using an exposure level that is unrealistic or biologically implausible in the name of "protecting a sub-population" will not increase safety, and may have the unintended unfortunate consequence of unnecessary loss of important crop protection tools.

3. **Promoting Safer, Effective Pest Control Methods**: We strongly support EPA's efforts to encourage wider adoption of strategies to use essential pesticides wisely and to reduce pesticide use where possible. At the same time, however, it is well known that many successful IPM and pest resistance management programs incorporate the careful use of existing pesticide products. Thus, it will remain critical that EPA's tolerance reassessment process and related decisions recognize the important role currently registered products will continue to play in these successful programs. It is equally important that the agency provide appropriate balance between the tolerance reassessment activities and the review of new products and new uses of registered products which can increase the availability to American agriculture of improved pest control tools. We are interested in hearing from you how this necessary balance and the associated levels of effort will be maintained.

4. **Openness**: This guiding principle speaks to open, fair, and consistent process of implementation, which should include stakeholder consultation in policy and program development. The single most frequently raised criticism we have heard is that EPA's implementation policies and processes have not been transparent, consistent, or communicated effectively or evenly to all stakeholders. If EPA does not take advantage of the opportunity to communicate effectively with stakeholders, we believe the Agency is missing an important opportunity to obtain more complete information with which to make timely and appropriate scientifically informed decisions. We are especially interested in hearing your perspective on this, and, in particular, in learning about EPA's schedule for rulemaking regarding the Agency's tolerance assessment decisions.

5. **Accountability**: To be publicly accountable for its actions under FQPA, EPA must incorporate the above-described principles in a credible and effective way. Unnecessary disruptions in domestic or international production and distribution of food products will not further this objective. The FQPA provided EPA important tools for enhanced public health protection, but also provided sufficient flexibility for the agency to use those tools in a balanced and reasonable way. We are aware of some who argue that EPA's success in implementing FQPA will be measured by the number of products or uses it removes from the market. We do not agree with this. This law in no way was intended as the beginning of an agency race to remove products from the market, but as the continuation and enhancement of responsible, reasoned, scientific decision-making, which balances public health goals with real needs of American agriculture.

We look forward to your response to the issues we have raised, and to continuing to work with you in implementing this important legislation.

Sincerely,

TOM BLILEY
CHAIRMAN

JOHN D. DINGELL
RANKING MEMBER

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 22 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Honorable John Dingell
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Congressman Dingell:

Thank you for your letter concerning the Environmental Protection Agency's (EPA) implementation of the Food Quality Protection Act (FQPA). I appreciate your interest in this important law and want to assure you that EPA is working to ensure that its provisions are implemented well in a timely manner to achieve greater food safety for U.S. consumers, particularly infants and children. In your letter, you ask the Agency to comment on our progress, any obstacles we may be facing, and how successful we have been in realizing the principles for implementation that we established.

FQPA provides a number of important provisions that enhance EPA's ability to protect consumers, particularly infants and children. These include aggregate and cumulative exposure, additional uncertainty factors, and use of a single, health-based standard for both raw and processed foods. As you mentioned, EPA developed several guiding principles. Specifically, EPA committed to: sound science supporting decisions; a health-based approach to food safety; the promotion of safer, effective pest control methods; openness; and accountability.

To ensure the continued commitment to these principles, the Vice President directed EPA to work together with the Department of Agriculture to ensure that implementation of FQPA is informed by a sound regulatory approach, by appropriate input from affected members of the public, and by due regard for the needs of our Nation's agricultural producers (memo attached). In response to this direction, we are establishing an advisory group, to be chaired by EPA Deputy Administrator Fred Hansen and USDA Deputy Secretary Richard Rominger, to seek advice and consultation from affected user, producer, consumer, public health, environmental, and other interested groups (memo attached). While we will be asking this group to help us establish a framework for EPA's decisions on the organophosphates, we expect that approaches pioneered by focusing on this group of chemicals can be applied broadly to all of our work in implementing FQPA. This advisory committee process will play an important role in helping to shape EPA policies and practices as we move forward with FQPA implementation.

I would like to describe our activities in support of each of these principles, our rationale, and our plans for the future.

Sound Science

EPA is committed to using the best available science in all our decisions. We have extensively used independent scientific review of significant technical and science policy issues to ensure that our policies incorporate the latest scientific advancements. The primary venue for this independent scientific review has been the Scientific Advisory Panel (SAP) established in FIFRA.

Since FQPA passed, this Panel has met five times (October 1996, February, March, and September 1997, and March 1998) to discuss aspects of EPA's implementation activities. The SAP has been very supportive of the Agency's interpretation of FQPA's science requirements. In addition, to obtain further independent advise on scientific issues related to FQPA, the Agency has worked with the International Life Sciences Institute (ILSI). ILSI conducted a case study on organophosphates to help establish when common mechanism should be considered, and is currently providing expert review of EPA's methods for considering drinking water exposures and for doing a cumulative risk assessment for organophosphates and carbamates.

While we are always interested in new information that could help us to refine our analyses, the Agency already has considerable data upon which to evaluate pesticides. As you know, within six months of FQPA's signing the Agency provided guidance on its interim approach to implementing the law's new provisions, which was developed in consultation with the Food Safety Advisory Committee convened to provide stakeholder input into the FQPA implementation process. In January of 1997, the Agency also outlined what additional information it would consider helpful in making regulatory decisions under FQPA, in a Notice sent to all pesticide registrants (PRN 97-1). Where registrants have chosen to submit supplemental data, it has been considered and incorporated into our risk assessments.

Concerns have been raised that the Agency may use unrealistic and inappropriate assumptions in risk assessments. This concern may be due in part to a misunderstanding of how the Agency uses modeling to screen potential risks. For example, when considering exposure through drinking water, if the Agency has specific data from monitoring or field trials, it conducts a refined risk assessment. In the absence of this type of data, EPA uses screening procedures to identify pesticides that are unlikely to reach drinking water at levels of concern to human health. Most pesticides are cleared in this screen. When a pesticide does not pass the screen, the Agency considers factors such as the nature of the human health concern, the overall risk posed by dietary exposures, and the magnitude of the potential contamination of drinking water. EPA does not rely on unrealistic, inappropriate assumptions but rather uses scientifically reviewed models to indicate which pesticides should be subjected to a more refined analysis.

EPA's goal is to develop the most practical way to make decisions on both old and new

chemicals. Where we are convinced that available data allows a decision that meets the FQPA standard, we will make that decision. Where the Agency believes it is necessary to invoke its data call-in authority, it will do so. It is important to note that the use of data call-in authority is not limited to the reassessment of existing tolerances. Applications for new chemicals and new uses would be subject to the same requirements as older chemicals. Older chemicals subject to reregistration should have a database comparable to new chemical and new use applications. EPA believes that it would not be responsible to wait for additional data if available information is sufficient to indicate what action should be taken. This applies equally to removing pesticides from the market, allowing continued use of an existing pesticide, or granting registrations to new pesticides.

Health-Based Approach to Food Safety

FQPA adopts a health-based approach to regulating pesticides on food. For example, the requirement of an additional tenfold margin of safety to account for potential enhanced pre- and post-natal sensitivity to toxicants and incomplete data related to children allows added confidence where the science is not certain. We believe the National Academy of Sciences (NAS) intended, and the law provides for, expansion of previous EPA practice in connection with use of additional uncertainty factors. Our goal in applying the safety factor has been to strictly adhere to the requirements of FQPA, using sound science and reliable information.

To provide additional clarity and to ensure that our decisions employ sound scientific evaluation and practices, the Administrator and Deputy Administrator have directed the Office of Prevention, Pesticides and Toxic Substances, in collaboration with the Office of Research and Development and the Office of Children's Health Protection, to evaluate the adequacy of the scientific database necessary for assessing risks to children and the decisions already made to ensure that they accurately reflect FQPA's intent. This memorandum also specifically directed the Agency to include appropriate external review and stakeholder consultation to ensure the transparency, adequacy of documentation, and consistency of EPA's decisions. An internal task force has been established to respond to this directive, and will be reporting back to the Administrator and Deputy Administrator on the progress and plans for these evaluations as well as a plan for seeking appropriate external review (memos attached).

It is clear that Congress intended for EPA to have a high level of confidence in the data available to assess children's risks. It is also clear that Congress recognized there would be instances where the additional uncertainty factor could be reduced by EPA. In my July 23, 1996, letter to Senator Richard Lugar, I wrote:

> "Under this provision, as an uncertainty factor, we would require an additional tenfold margin of safety if the Agency does not have complete and reliable data to assess pre or postnatal toxicity relating to infants and children, or the data indicate pre or postnatal effects of concern. When the data are incomplete, we use an

additional uncertainty factor between three and ten based on how much information is incomplete. The data EPA would consider include data submitted in compliance with EPA testing requirements, available data published in the scientific literature, and any other data available to EPA and meeting general scientific standards. Where reproductive and developmental data have been found acceptable to EPA, and the data do not indicate potential pre or postnatal effects of concern, the additional tenfold margin of safety would not be applied."

As you know, the law requires EPA to begin with the assumption that the factor should be retained. In some cases, the Agency has reduced or removed the safety factor using a weight-of-evidence approach, considering the completeness of the database and any pre- or post-natal effects of concern. This approach has been supported by the pesticide program's Scientific Advisory Panel (SAP). Each tolerance decision is published in the Federal Register and contains discussions of what factor was used, the rationale supporting that choice, and what steps were taken to ensure that the tolerance was protective of children and infants.

When evaluating the need to retain the additional factor, EPA considers the entire toxicity database. This database includes at least one reproductive toxicity study and two developmental toxicity studies, as well as other acute, subchronic, and chronic studies which are generally required for food use pesticides. In addition, the Agency may require acute, subchronic, and developmental studies for chemicals where neurotoxic modes of action are indicated. While other studies may contain information useful in assessing the safety of infants and children, the developmental and reproduction studies and developmental neurotoxicity study where needed are particularly important in this assessment.

Once studies have been reviewed by individual scientists, EPA scientific peer review groups assess all of the data to determine its adequacy and to assure that infants and children are protected. If further expertise is needed after internal peer review, an outside panel such as the SAP will be consulted. If for any reason the Agency decides that available data do not allow a refined assessment of the safety of infants and children, the tolerance will either not be granted or an additional uncertainty factor will be used. Where an additional factor is used, further data may be requested and the factor might be adjusted if new data are generated. Under no circumstances would a tolerance be granted where the FQPA standard is not met.

EPA has required, by regulation, a basic core set of toxicity and exposure data since 1984. The NAS report served to point out new directions for the Agency but the bulk of the data required for us to make these decisions have been part of our registration and tolerance decision-making process for some time. Our decisions have used available, reliable data in determining how much, if any, of the additional factor to remove. We have retained the full factor where we feel the data are insufficient to determine that a factor less than ten will be protective.

We are currently reassessing the tolerances of a significant number of pesticides which

EPA has determined, as instructed by FQPA, present the greatest potential risk in food. We have presented more detailed criteria for use of additional safety factors, and a set of case studies to illustrate the criteria, to the SAP (March 24-25), in response to their suggestion that the Agency refine its policies as experience with the new standard increased.

In your letter, you state your belief that FQPA excludes a "bright-line" definition of acceptable lifetime risk. This approach to lifetime risk allows for flexibility in science as quantitative risk assessment methods improve, a principle to which EPA is committed.

You also expressed your concern that EPA confirm statistical reliability of upper-limit exposure information. Here again, EPA is committed to the use of sound science in our use of upper-limit exposure information. It might be helpful to clarify our current approach to this issue.

For dietary exposure, for example, EPA continues to regulate at the 95th percentile where risk assessments add each food item separately. EPA believes that this practice results in a conservative level of protection, because in reality one is unlikely to consume several foods at the 95th percentile level. Where registrants provide probabilistic risk assessment methods to more accurately estimate consumption patterns of several food items in the diet, the Agency uses 99.9th percentile exposure values. EPA believes this practice is warranted because these more refined analyses greatly increase the confidence that we are accurately assessing risks over the entire population, including special subpopulations such as infants and children. In practice, risk assessments done at the 99.9th percentile for a mixture of foods can be expected to result in lower estimated risk than risk assessments done by adding together the 95th percentile consumption of each food.

Promotion of Safer, Effective Pest Control Methods

EPA recognizes that bringing new and safer technologies to the marketplace is an essential component of our efforts to reduce the potential risks from pesticide exposures while helping to maintain an abundant and safe food supply. FQPA adds new emphasis to these important efforts. As you may know, the Agency had created a new reduced-risk pesticide registration program to facilitate this effort before FQPA was enacted.

Through the reduced-risk program, EPA screens applications for new pesticides and new uses which claim to be reduced-risk alternatives to conventional pesticides, and expedites the review of applications which pass the screen. The average time for review of a reduced risk chemical is approximately 14 months, where the average time for a review of a conventional chemical pesticide is approximately 38 months. Since its inception during Fiscal Year 1994, EPA's reduced-risk program has received 48 submissions for new active ingredients, of which 30 passed the reduced risk screen. Of the 30 applications which were accepted, 16 have been registered and 14 are under review.

In addition to our efforts in the reduced risk program, EPA has been working hard to bring other new and safer products to the market. Since FQPA was enacted, we have registered 33 new synthetic chemical active ingredients, six new products in the Biopesticide and Pollution Prevention Division, and two new antimicrobial active ingredients.

We recognize that, given the complexity of FQPA and the lack of a phase-in period for implementation, there was an initial delay in registrations for some of the reduced-risk pesticides and for some new uses. This delay was, in part, due to the significant amount of resources required to establish tolerances for emergency exemptions. As we have gained more experience, and with the work already done for repeat emergency exemptions, we expect significant improvements in the pace of these actions.

Let me assure you we are very much aware that the decisions we make can have real effects on farmers and other pesticide users. All decisions will be communicated clearly to congress, farmers, and other stakeholders. The challenge we all face is in establishing an orderly process that will allow us to meet the mandates of FQPA while ensuring that producers have access to the tools they need to ensure a wholesome, adequate, and safe food supply. We will work with growers, the Department of Agriculture, the registrants, and the research community to ease this transition so that as older products leave the marketplace new methods are made available. We are especially mindful of the potential impacts on minor crop growers and integrated pest management programs and will continue to work with growers and registrants to focus attention on those situations where limited crop protection alternatives exist.

Openness

As we move forward with implementation, EPA is committed to a process grounded in the best available science and allowing for broad stakeholder input. Given the immediate effective date for the law, resulting in considerable changes to existing Agency procedures, our approaches are still evolving. We want to make every effort to see that our policies are developed with input from stakeholders. Immediately after the law was signed, EPA established the Food Safety Advisory Committee to provide input on our interim approach to risk assessment and to help us prioritize implementation activities. This group, which met four times between September and December 1996, was comprised by a wide range of parties representing industry, environmental groups, growers, and Congress (including your Committee). The Agency has presented its risk assessment approaches to the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP), and we will continue to seek outside peer review of significant science policy issues. EPA formed the Endocrine Disruptor Screening and Testing Advisory Committee to coordinate FQPA's endocrine disruptor provisions. We have also worked with the International Life Sciences Institute on a case study for cumulative exposure.

As I mentioned earlier, EPA is establishing a new advisory committee to ensure broad stakeholder involvement in the FQPA implementation process. Of particular interest to this

group will be EPA policies and practices relating to the tolerance reassessment of the organophosphate pesticides (OP's). Because of the importance of the reassessment of the OP's -- both in terms of public health protection and agricultural production -- significant stakeholder input will be key to the development of a fair, common sense approach to regulating the OP's under FQPA.

EPA's schedule for rulemaking on tolerance assessment decisions was outlined in an August 4, 1997, Federal Register notice (copy enclosed). FQPA requires EPA to reassess all existing tolerances within ten years, with milestone deadlines every three years, to ensure that they meet FQPA's new standards. At this time, we expect to be able to meet the ambitious schedule laid out in the statute. Let me assure you that in doing so, our decisions on these and all other chemicals will continue to be based on sound science and reliable information. In addition, as I mentioned earlier, the Administrator and Deputy Administrator directed a review of our implementation of the additional uncertainty factor to ensure that our decision making process is transparent, well documented, and consistent.

Accountability

We agree that our decisions must be credible and effective, take advantage of sound science, and be publicly accountable. We are committed to these principles. The Agency believes our actions to this point have reflected this commitment and in no way reflect a "...race to remove products from the market." In all our actions we will strive to ensure adequate stakeholder input, the application of sound science, the use of appropriate external review, and open communication with all of our stakeholders.

FQPA is a safety standard which will result in changes to existing pesticide registrations. Our role is to make certain that the process driving these changes is sound, reasonable, and makes every effort to balance the need to meet FQPA's standard with the importance of maintaining adequate tools for producers.

Thank you again for your continuing interest in the implementation of this important new law. For further information, I have enclosed our report "FQPA: Status of Implementation at the End of Fiscal Year 1997," which details Agency achievements in implementing FQPA.

Sincerely yours,

Lynn R. Goldman

Lynn R. Goldman, M.D.
Assistant Administrator

Enclosures